

REMARKS

Entry of the Amendment, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.111, are thus respectfully requested.

1. Status of the Claims

Claims 1-9, 12, 13, and 16-28 stand pending. Claims 1-9, 12, 13, and 16-28 stand rejected. After entry of the above amendments, claims 1-9 and 23 stand pending with claims 1, 4, 5, and 23 having been amended. Claims 10-22 and 24-28 stand canceled. The amendments in claims 1, 4, 5, and 23 are made to conform claims to U.S. practice formalities. Applicants have submitted amendments without prejudice to or disclaimer of the canceled subject matter. Applicants reserve the right to file a divisional or continuation application on any subject matter canceled by way of amendment.

Support for the foregoing amendments can be found, for example, in at least the following locations: the original claims and the specification, page 12, lines 25-37; page 27, Table 2 and page 51, Table 17.

2. Certified Priority Documents

Applicants note the indication that all certified priority documents have been received in this application.

3. Objection the Claims

The Examiner states that the objection to claims 4 and 10-13 is maintained. Claims 10-13 are canceled, and therefore the objection is moot. Claim 4 as amended more clearly sets forth that the claim is a process claim, and not a product-by-process claim. Therefore, for at least these reasons the objections to the claims should be withdrawn.

4. Rejection of the Claims Under 35 U.S.C. § 102(b)

Claims 16-22, 24, and 27-28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,117,905 to Higashiyama et al (hereafter "*Higashiyama*").

Applicants respectfully traverse the rejection. To establish a *prima facie* case of anticipation, a single prior art reference must teach each and every element of the claimed invention, either explicitly or inherently. *Verdegaal Bros. v. Union Oil Co. Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Claims 27 and 28 each recite that the crude oil or refined oil, respectively, has a triglyceride content of 90% by weight or more. *Higashiyama* at least fails to disclose this element. *Higashiyama* discloses lipid containing about 70% by weight or more triglyceride and about not more than 30% by weight phospholipids. *See, e.g.*, col. 5, ll. 45-47. For an overlapping range to anticipate a claimed range, the prior art range must anticipate the claimed range with "sufficient specificity." *See* MPEP § 2131.03. There is no disclosure of any triglyceride percentage substantially higher than 70% by weight nor disclosure of any lipid with substantially less phospholipids than 30% by weight. Thus, *Higashiyama* fails to provide any evidence to support a finding that the claimed range is disclosed with "sufficient specificity." For at least this reason, at least one of the elements of each of claims 27 and 28 are not disclosed by *Higashiyama*, and thus the rejection is improper.

Applicants further note that silence to ester type sterol content is not a disclosure of 0.0% ester type sterol as alleged by the Office. *Higashiyama* fails to disclose what the ester type sterol content of the oil is. Therefore, the silence of *Higashiyama* cannot be used as a disclosure of less than 0.8% ester type sterol.

Dependent claims 18-22, 24, and 29-30, which depend from claims 27 or 28, respectively, are also not anticipated for at least reasons similar to those for claims 27 and 28. For at least these reasons the rejection should be withdrawn.

5. Rejection of the Claims Under 35 U.S.C. § 103(a)

Claims 1-9, 12-13, and 16-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP-957173 (hereafter "EP '173") in view of JP-06/105680 (hereafter "JP '680"). The Examiner alleges that EP '173 discloses a crude oil with increased highly

unsaturated fatty acid and decreased amount of ester type sterol produced by culturing the microorganism with a medium containing a nitrogen source. The Examiner further alleges that EP '173 discloses that aeration and agitation are important to culturing, and that JP '680 discloses a ratio of impeller diameter to the inside of the tank diameter.

Applicants respectfully traverse. Whether a claim is obvious is based on an objective analysis of the scope and content of the prior art, the differences between the prior art and each element of the claimed invention, and the level of skill in the pertinent art. *See Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966). The Office's objective analysis of obviousness should be made explicit. *See KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). The rejection is improper, at least because not all of the limitations in claim 1 are disclosed or suggested by either EP '173 or JP '680, and any combination of the two references is impermissibly made solely from hindsight reasoning.

A. Neither EP '173 nor JP '680 disclose the claimed nitrogen source concentration.

Claim 1 recites "culturing the microorganism in a medium containing a nitrogen source concentration of 2 to 15%." EP '173 and JP '680 each fail to disclose or suggest a nitrogen source concentration within the claimed range. JP '680 drawn to a culturing apparatus for animal cell production and not microorganisms is silent to any nitrogen source concentration. The Examiner appears to rely on EP '173 for the nitrogen source concentration. However, EP '173 only discloses nitrogen source concentration in the medium in the Examples, with no generic disclosure. The Examples do not teach adding any nitrogen source to the medium in an amount greater than about 1.5%. *See, e.g.*, Examples 1-4, paragraphs 42-48. The Examiner may have been incorrectly relying on paragraph 21 of EP '173, which discloses the nitrogen concentration in the desired nitrogen source. However, this concentration is not the amount of nitrogen source in the medium.

Further, EP '173 fails to suggest increasing the nitrogen source concentration. EP '173 is concerned with producing increased highly unsaturated fatty acid concentrations with decreased 24,25-methylene-cholest-5-en-3 β -ol concentration. *See, e.g.*, p. 3, para. 12. EP '173 meets this objective by using soybean as the particular nitrogen source. *See, e.g.*, p. 3, paras. 20-21. EP

‘173 fails to recognize the nitrogen source concentration as a result effective variable.

EP ‘173 describes nitrogen source concentrations of about 1.5% or less. *See, e.g.,* Examples 1-4, paragraphs 42-48. Low nitrogen source concentrations as used in EP ‘173 are conventional concentrations used to produce highly unsaturated fatty acids with lower unsaponifiable matter, and conventional wisdom was that increasing the nitrogen source concentration to increase the amount of fat or oil produced would also increase the unsaponifiable matter and sterol content. *See, e.g.,* Specification p. 8, ll. 14-35. Therefore, one of ordinary skill in the art with conventional knowledge and the disclosure of EP ‘173 would not expect success in increasing the nitrogen source concentration to 2-15%. Applicants were able to use the higher nitrogen source concentration, because of the particularly claimed impeller design used in the culturing process. *See, e.g.,* Specification p. 8, l. 36 – p. 9, l. 15. Therefore, neither EP ‘173 nor JP ‘680 disclose or suggest to one of ordinary skill in the art the use of 2-15% nitrogen source concentrations in the microorganism culturing medium as claimed. At least because the references fail to teach at least the nitrogen source concentration, the rejection is improper. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

B. The Examiner has impermissibly used hindsight reasoning to combine EP ‘173 and JP ‘680, and allege obviousness of the claims.

Using the claimed invention as a roadmap to find its prior art components is impermissible hindsight reasoning. *Princeton Biochemicals Inc. v. Beckman Coulter Inc.*, 75 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 2005). Independently selecting and choosing elements of the claims is impermissible in assessing obviousness, because 35 U.S.C. § 103 requires assessment of the invention as a whole. *Ruiz v. A.B. Chance Co.*, 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004). The “as a whole” assessment of the invention requires a showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements in the prior art, and combined them in the claimed manner. *Princeton Biochemicals Inc. v. Beckman Coulter Inc.*, 75 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 2005). The Office fails to provide any rationale for

why one of ordinary skill in the art without using the claims as a roadmap, would select the particularly claimed ratio of the impeller diameter to the inner diameter of the culture tank. One of ordinary skill in the art, without the knowledge of the claimed invention, would not have selected the claimed ratio of the impeller diameter to the inner diameter of the culture tank.

EP '173 provides no suggestion that a particular agitation impeller design or a particular aeration and oxygen concentration affects highly unsaturated fatty acid, unsaponifiable matter or sterol concentrations. The only mention of agitation or aeration in EP '173 is that the microorganism is cultured in a fermentor with aeration. *See, e.g.*, p. 3, paras. 11-12 (also cited by the Examiner). However, this statement is merely disclosing the conventional method of culturing microorganisms in a fermentor with aeration, and not describing any particular importance to the aeration and agitation parameters of the fermentor. Because EP '173 discloses using a conventional fermentor, the ratio of d/D is also conventional where the ratio of d/D is smaller than the ratio recited in the claims. EP '173 fails to disclose, as opined by the Examiner, that manipulation of the aeration and agitation parameters are variables to manipulate in order to control the highly unsaturated fatty acid, unsaponifiable matter, or sterol concentrations of the produced oil. Therefore, EP '173 fails to suggest to one of ordinary skill in the art that aeration and agitation parameters are variables affecting the desired oil concentrations, much less that a particular ratio of impeller diameter to inner tank diameter provides advantageous culturing of highly unsaturated fatty acids with low unsaponifiable matter and sterol concentrations.

The Examiner has further relied on JP '680 for the disclosure of a culture tank having an impeller diameter to inner tank diameter ratio between 0.25 and 0.375. *See, e.g.*, JP '680 Abstract. However, JP '680 is a culture tank for producing animal cells and not microorganisms. Animal cell and microorganism production differ in that the mechanical strength of a cell is weak compared to a microorganism with regards to churning and foaming. *See, e.g.*, English machine translation of JP '680, para. 4. JP '680 merely discloses that a conventional microorganism culturing apparatus cannot be used for the culture of animal cells. *See, e.g.*, English machine translation of JP '680, para. 4. The particular impeller diameter to inner tank diameter ratio disclosed in JP '680 is specially developed for animal cell production, and in contrast to conventional microorganism culture tanks. *See, e.g.*, English machine translation of

JP '680, paras. 7-8. Therefore, there is no expectation of success in applying the same ratio to microorganism culture tanks, when JP '680 suggests the ratio is specially developed for animal cells, and the problem solved by the ratio is not relevant to microorganism culturing. Thus, JP '680 fails to suggest to one of ordinary skill in the art to culture microorganisms within a culture tank equipped with an agitation impeller that satisfies the claims.

Applicants discovered the link between the ratio of agitation impeller to the inner diameter of the culture tank and the ability to form higher concentrations of highly unsaturated fatty acid containing oil with low unsaponifiable matter and ester type sterol content. *See, e.g.*, Specification p. 9, ll. 1-15. The Examiner has impermissibly used this newly discovered link described solely by Applicants to combine the particular ratio disclosed in JP '680 with the invention of EP '173. The Examiner has failed to provide any other rationale for combining the teachings, especially in light of the disclosure in JP '680 explicitly limiting the desire to manipulate the diameter of the agitation impeller to animal cell production and not microorganism production. Further, because Applicants newly discovered the link between the ratio and the desired oil production, it would not be merely within the common knowledge of one of ordinary skill in the art to use the particularly claimed ratio. For at least the above reasons, one of ordinary skill in the art, without the knowledge of the claimed invention, would not have selected the claimed ratio of the impeller diameter to the inner diameter of the culture tank, and thus the rejection is improper.

Dependent claims 2-9 and 23, which depend from claim 1, are also not obvious for at least the same reasons as for claim 1. For at least these reasons, no *prima facie* case of obviousness has been established, and the rejection should be withdrawn.

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CONCLUSION

In conclusion, this is believed to be in full response to the outstanding Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573.

Respectfully submitted,
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